Attorney Docket No. MP/143

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Walter
Appl. No. : 09/369,231
Filed : August 5, 1999
Title : Surface Modified Expanded Polytetrafluoroethylene Devices and Methods of Producing the Same

I hereby certify that this correspondence is being facsimile transmitted to the Patent and Trademark Office on June 5, 2003.

Melanee Williams
Melanee Williams

Group Art Unit: 1771
Examiner : H. Vo

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF JAMES T. WALTER

Sir:

1. My name is James T. Walter and I am the named inventor in the above application. I have over 18 years of engineering experience with W. L.. Gore & Associates, Inc., specializing in PTFE and PTFE processing within the medical device industry. I am the named inventor on four issued United States Patents, D445,188, D444,878, 5,858,505, and 5,601,691, and in multiple pending applications.

2. I attended an interview concerning the present application at the United States Patent and Trademark Office on May 29, 2003. During the interview I explained that the structure claimed in the present application is markedly different over the structure that can be produced by the process described in United States Patent 4,734,112 to Okita et al. As is taught in the present application, the present invention produces a unique surface structure having gnarled nodes situated between nodal clusters wherein the gnarled nodes are substantially devoid of fibrils along their protruding lengths. The present invention can also be described as having a structure whereby the protruding length of the fibril-less node has length that is greater than the height of adjacent ridges. These structures were shown at the interview as product samples, experimental samples, and in photomicrographs.

3. At the interview I explained that the structure of the present invention is achieved by modifying conventional laser equipment t int ntionally unfocus a laser beam. As is shown in attached Exhibit 1, a conventional focused laser beam concentrates a tremendous amount of

energy to a very small area by using a focusing lens. By contrast, as is shown in Exhibit 2, the unfocused laser beam used to produce the material of the present invention produces a very wide, low powered beam with a gradient of decreasing laser power around its edges. Exhibit 3 shows the effect of this wide, low powered beam in producing the inventive structure illustrated in Figure 4E of the present application. This is in comparison to the high-powered focused beam of the prior art that simply will cut through the material without uniquely modifying the nodal structure in the manner claimed.

4. At the interview I presented a first sheet of expanded PTFE material that had been modified in accordance with the Okita et al. patent and the teachings of the present invention. This first sheet was a relatively open-structure ePTFE material as described on page 11 of the present application. This material was treated both with an unfocused laser in accordance with the present invention and with a focused laser at different power settings in accordance with Example 3 of the Okita et al. patent. As was shown, the focused laser at normal power settings cut right through the ePTFE material. As the power was reduced, the laser no longer cut-through the ePTFE material, but instead created a series of finely grooved partial perforations in the surface of the material. This structure is illustrated in the photomicrographs in the lower half of Exhibit 4. The sample shown at the interview and illustrated in Exhibit 4 demonstrated that the unique nodal structure of the present invention as shown in the upper half of Exhibit 4 and as claimed in the present application is not present when the base material is treated in accordance with the prior art.

5. I next presented a second sheet of expanded PTFE material that had been modified in accordance with the Okita et al. patent and the teachings of the present invention. This second sheet was a relatively closed-structure ePTFE material similar to that described in Example 3 of the Okita et al. patent. Again, this material was treated both with an unfocused laser in accordance with the present invention and with a focused laser at different power settings in accordance with Example 3 of the Okita et al. patent. Once again, the focused laser at normal power settings cut right through the ePTFE material. As the power was reduced, the laser created a series of finely grooved partial perforations in the surface of the material. This structure is illustrated in the photomicrographs in the lower half of Exhibit 5. The sample shown at the interview and illustrated in Exhibit 5 demonstrated that the unique nodal structure of the present invention as claimed in the present application is not present when this second base material is treated in accordance with the prior art.

6. The procedures taught in the Okita et al. patent do not result in a surface structure in any way similar to the structure taught and claimed in the present application. The structures

claimed in the present application cannot be achieved using a focus d laser beam as taught in the prior art.

I hereby declare that all statements made herein of my own knowledge are true and that the statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: June 6, 2003

James T. Walter

EXHIBIT 1

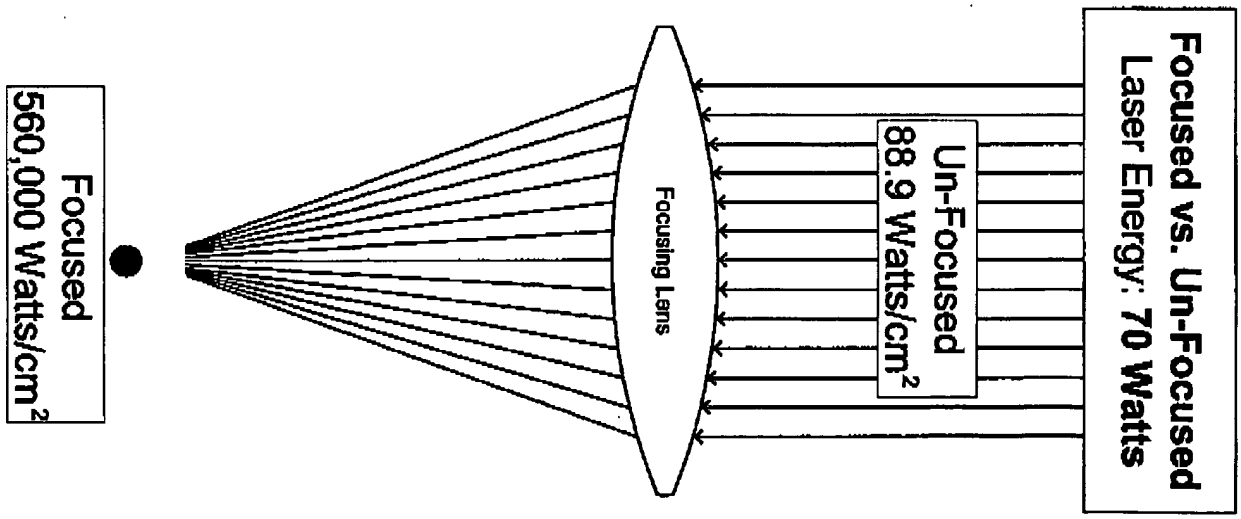


EXHIBIT 2

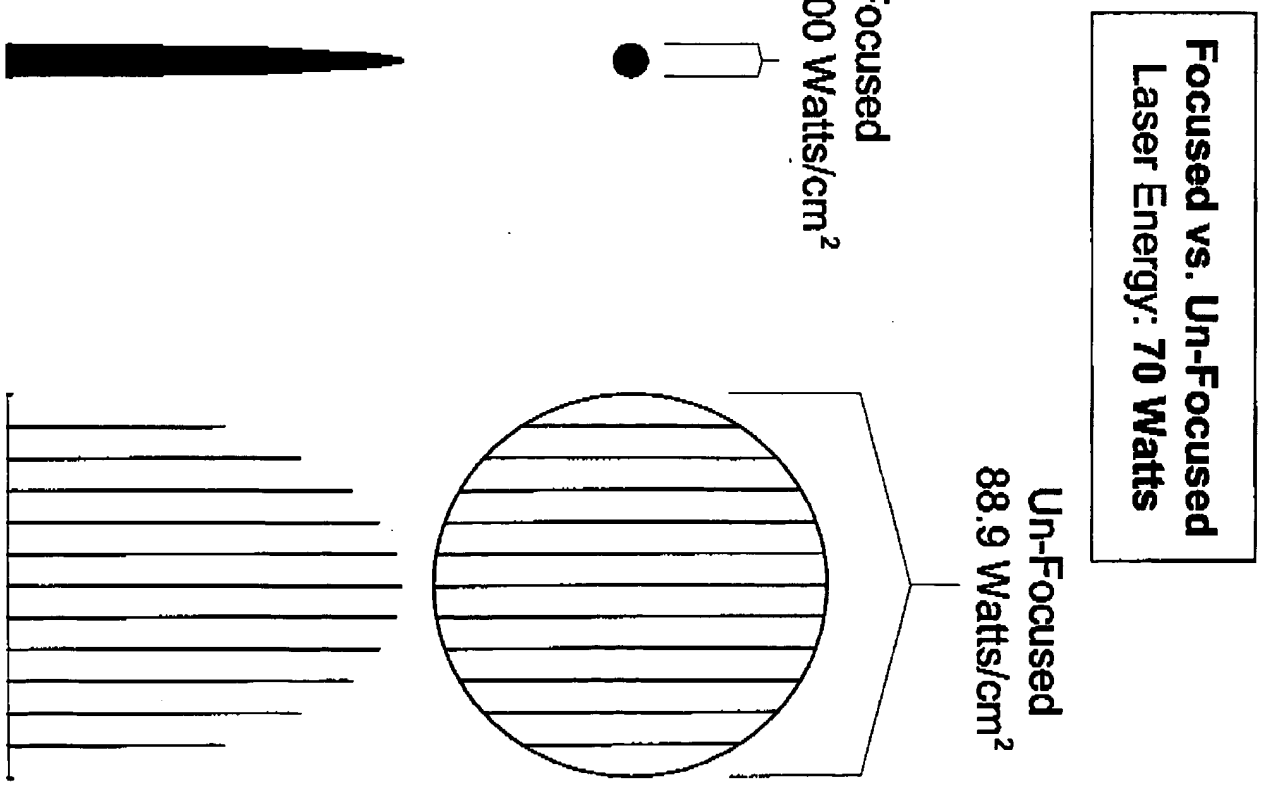
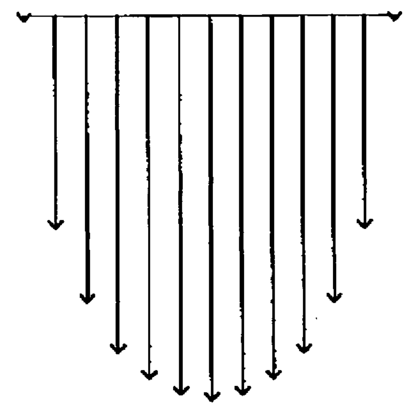

Focused vs. Un-Focused
Laser Energy: 70 Watts
Focused
560,000 Watts/cm²
Un-Focused
88.9 Watts/cm²

EXHIBIT 3

Focused vs. Un-Focused
Laser Energy: **70 Watts**

Focused
560,000 Watts/cm^2

Un-Focused
88.9 Watts/cm^2



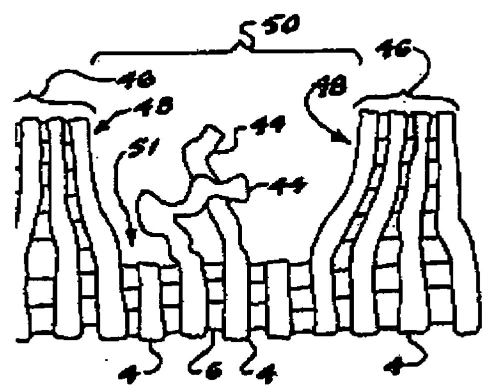


Fig. 4E

EXHIBIT 4

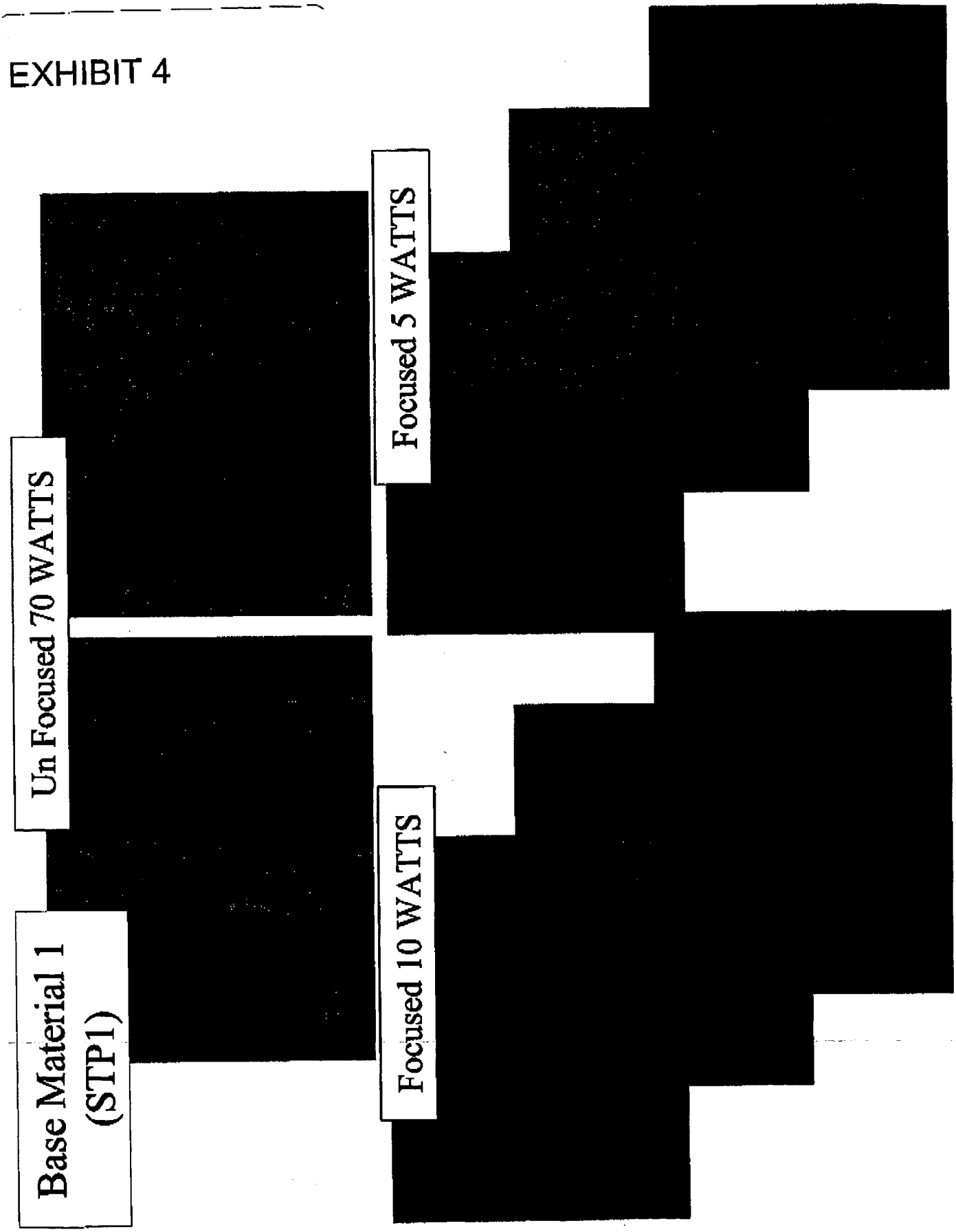


EXHIBIT 5